REMARKS

Claims 1-5, 15, 19-39, 103 and 104 are pending. Claims 6-14, 16-18, 31, 42-51, 53-55, 60, 68-71, 79-80, 85-97, 102 were previously canceled, without prejudice. Claims 30, 32-39 and 103 are canceled, without prejudice. Claims 40-41, 52, 56-59, 61-67, 72-78, 81-84, 98-101 and 103 were previously withdrawn as being drawn to a non-elected invention. Applicants expressly reserve their right to pursue the withdrawn claims in a separate application.

Claims 3 and 20 were amended to more clearly claim what Applicants consider to be their invention

Claim 3 was amended to depend from claim 104. Support can be found at least in original claim 3.

Claim 20 was amended to recite "The composition of claim 2, further comprising a preservative,". Support can be found at least in paragraphs [0146] and [0244] of the published application where preservatives are described.

RESPONSIVE REMARKS

Double Patenting

The Office Action states that should claim 103 be found to be allowable, claim 104 will be objected to under 37 C.F.R. 1.75 as being a substantial duplicate thereof. Applicants note that claim 103 has been canceled. Applicants submit that the cancelation of claim 103 renders the potential rejection moot.

Objection to the Specification

Applicants have amended paragraphs [0028], [0029] and [0034] of the specification of the published application. Applicants respectfully submit that the amendments to paragraphs [0028], [0029] and [0034] of the specification of the published application renders this objection moot. Applicants respectfully request that the Examiner withdraw these objections.

Claim Rejections- 35 USC § 101

Claims 36, 38 and 39 are rejected under 35 U.S.C. 101 because the claimed invention is allegedly directed to non-statutory subject matter. Applicants note that claims 36, 38 and 39 have been canceled. Applicants submit that the cancelation of claims 36, 38 and 39 renders the rejection moot.

Claim Rejections - 35 USC § 112

Claims 20 and 36-39 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse this rejection to the extent that the rejection applies to the claims as amended.

Claim 20 has been amended to recite "The composition of claim 2, further comprising a preservative, wherein the preservative comprises benzyl alcohol, a paraben and phenol, or a mixture thereof." Applicant submits that the amendments to claim 20 render this rejection moot. Therefore, Applicant respectfully requests that the Examiner withdraw this rejection and allow this claim.

Claims 36-39 have been canceled. Applicants submit that the cancelation of claims 36-39 renders the rejection moot.

Rejection Under 35 U.S.C. § 102

1. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Owen et al. (US 2003/0198452). Applicants respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131. Thus, if a cited reference omits even a single element recited in the pending claims, it cannot anticipate. As set forth below, Owen et al. fails this test.

Claim 1 recites:

> A composition comprising erythropoietin and an erythropoietin production inducing peptide (EPIP).

As defined in the instant specification, EPIPs are "peptides that are capable of directly or indirectly stimulating proliferation of fibroblasts, which in turn produce erythropoietin." (Emphasis added). Thus, an EPIP is a peptide that induce production of erythropoietin.

Owen et al. describes FLAK peptides and their effect on human fibroblast cells. FLAK peptides are short length peptides containing phenylalanine, leucine, alanine, and lysine amino acids (F, L, A and K).

Owen et al. does not disclose or suggest that FLAK peptides induce production of erythropoietin. Owen et al. merely shows that the FLAK peptides stimulate the proliferation of fibroblasts, and claim that they are useful as antibacterial, antifungal, anticancer, and in other biological applications. The Office Action appears to suggest that because the FLAK peptides stimulate the proliferation of fibroblasts, they must, in turn, make erythropoietin. Applicants submit that such an assumption is fatal to the Office Action's arguments.

Applicants respectfully submit that fibroblasts, as a general rule, do not produce erythropoietin, even when they are stimulated to proliferate. Even in the kidney only a subset of peritubular fibroblast-like cells produce erythropoietin (see Discussion in Kishore et al., *American Journal of Physiology Renal Physiology* 292: F749-F761, 2007). Furthermore, the biology of these erythropoietin-producing cells is not fully understood. Conversely, although proliferation of peritubular cells in the kidney is known to occur in several conditions, such as post-obstructive uropathy, administration of aminoglycoside antibiotics, and other agents, yet none of these conditions induce production of erythropoietin (see Discussion in Kishore et al., *Laboratory Investigation* 74:1013-1023, 1996a). Thus induction of proliferation of peritubular fibroblast-like cells, associated with production of erythropoietin, is a distinctive feature of the claimed invention, which does not mimic any other known substance to date. As such, the Office Action's reasoning that simply because Owen et al. shows that FLAK peptides stimulate the production of fibroblasts, they must also induce production of erythropoietin, is flawed. Absent such an inherent or express link between stimulate the production of fibroblasts and induction of the production of erythropoietin, Applicants submit that Owen et al. fails to disclose every feature of claim 1. Therefore, Owen et al. fails to anticipate claim 1. As such, Applicants respectfully request withdrawal of the rejection of claim 1.

2. Claims 2, 4, 15, 19 and 29 are rejected under 35 U.S.C. § 102(e) as being anticipated by Mekalanos et al. (US 2003/0108556). Applicants respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131. Thus, if a cited reference omits even a single element recited in the pending claims, it cannot anticipate. As set forth below, Mekalanos et al. fails this test.

Claim 2, from which claims 4, 15, 19 and 29 depend, recites:

> A composition comprising an erythropoietin production inducing peptide (EPIP), wherein the EPIP comprises poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid, poly-L-aspartic acid, or a mixture of both.

As defined in the instant specification, EPIPs are "peptides that are capable of directly or indirectly stimulating proliferation of fibroblasts, which in turn produce erythropoietin." Thus, an EPIP is a peptide that induce production of erythropoietin.

The Office Action relies on Mekalanos et al. for disclosing the "D" isomer of polyglutamic acid. The Office Action admits that Mekalanos et al. is silent regarding the EPIP-inducing characteristics of poly-D-glutamic acid, but meet the claimed limitations since the polymer is disclosed. Applicants respectfully disagree.

First, Makalanos et al.'s discloses therapeutic methods and compositions for targeting an infectious agent, such as bacteria, by conjugating various therapeutic agents to polymeric materials, such as poly-D-glutamic acid, as carriers. In other words, Makalanos et al. merely teaches the use of poly-D-glutamic acid as a carrier, while the desired effect is brought about by the therapeutic agent conjugated to the carrier. In this respect, it should be noted that polymeric compounds such as polyglutamic acid, and other polyamino acids, as well as dextrans have been

used to deliver not only anti-infectious agents, but also anti-cancer drugs (McCormick-Thomson and Duncan, *Bioactive and Compatible Polymers* 4:242-251, 1998; and McCormick-Thomson et al, *Journal of Bioactive and Compatible Polymers* 4:252-268, 1989). However, none of those studies, including the one by Makalanos et al. disclose or suggest that such use of poly-D-glutamic acid as a carrier induced proliferation of peritubular fibroblast-like cells in the kidney that is associated with the production of erythropoietin.

Second, paragraphs [0131] to [0135] of Makalanos et al. describe the preparation of covalently bound conjugates of poly-D-glutamic acid with an anti-infectious agent, using carbodiimide reaction, which is a standard procedure in synthetic organic chemistry. While doing so Makalanos et al. is actually producing a modified poly-D-glutamic acid, whose γ-amino groups are blocked to varying degrees. Furthermore, the binding of anti-infectious agents of different molecular masses also changes the molecular mass and structure of poly-D-glutamic acid. Put simply, the obtained conjugate is bound to have physical and chemical structures, and pharmacological and biological activities that are distinctly different from poly-D-glutamic acid. In fact, such a conjugate cannot be considered poly-D-glutamic acid any more. As such, Makalanos et al. merely describes a polymer that contains a carrier that is not poly-D-glutamic acid once the polymer is formed. In other words, Makalanos et al. fails to disclose a composition comprising an erythropoietin production inducing peptide (EPIP), wherein the EPIP comprises poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid, poly-L-aspartic acid, or a mixture of both. As such, contrary to the Office Action's allegations, Makalanos et al. fails to disclose subject matter which naturally includes functions that are newly cited or are identical to the currently claimed composition. Applicants therefore submit that the current rejection fails the tests described in *In re Best* and *In re Fitzgerald* cited in the Office Action.

For all the reasons described above, Applicants submit that Makalanos et al. fails to disclose every feature of claims 2, 4, 15, 19 and 29. Therefore, Makalanos et al. fails to anticipate claims 2, 4, 15, 19 and 29. As such, Applicants respectfully request withdrawal of the rejection of claims 2, 4, 15, 19 and 29.

3. Claims 1-5, 19, 21, 23-24, 26, 29, 30, 33-35, 37-39, 103 and 104 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fewell et al. (WO 01/66149) in view of evidence from the 1998 Sigma Catalog. Applicants respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131. Thus, if a cited reference omits even a single element recited in the pending claims, it cannot anticipate. As set forth below, Fewell et al. fails this test.

Claims 30, 37-39 and 103 have been canceled. Applicants submit that the cancelation of claims 37-39 and 103 renders the rejection moot.

Claim 1

Claim 1 recites:

> A composition comprising erythropoietin and an erythropoietin production inducing peptide (EPIP).

As defined in the instant specification, EPIPs are "peptides that are capable of directly or indirectly stimulating proliferation of fibroblasts, which in turn produce erythropoietin." (Emphasis added). Thus, an EPIP is a peptide that induce production of erythropoietin.

Fewell et al. describes the ability of poly-L-glutamate to increase the expression of a non-viral erythropoietin gene where a plasmid containing the mEPO coding sequence was formulated in poly-L-glutamate. The results of injecting mice with the poly-L-glutamate formulated plasmid

showed that mEPO expression was increased as compared to mice injected with a plasmid containing the mEPO coding sequence was formulated in saline.

The Office Action alleges that the ordinary artisan would reasonably conclude that the cells comprise poly-L-glutamic acid and the celss are capable of expressing Ep due to the presence of the Ep-encoding vector and therefore Fewell et al. meets the limitations of claim 1. Applicants submit that such a reasoning is flawed.

First, as described above EPIPs are peptides that are capable of directly or indirectly stimulating proliferation of fibroblasts, which in turn produce erythropoietin. Nowhere, in Fewell et al., is there any descritpition or suggestion that fibroblast proliferation was stimulated by the poly-L-glutamate formulated plasmid. The Office Action has completely overlooked this limitation. EPIPs are not simply peptides that produce erythropoietin themselves, like the poly-L-glutamate formulated plasmid of Fewell et al.. EPIPs are peptides that directly or indirectly stimulating proliferation of fibroblasts, which in turn produce erythropoietin. At least for this reason, Fewell et al. fails to anticipate claim 1.

Applicants further submit that Fewell et al. states:

> In one embodiment of the invention, the disease is characterized by insufficient levels of red blood cells resulting in anemia. Delivery of a nucleic acid encoding erythropoietin ("EPO") formulated in poly-L-glutamic acid and delivered in conjunction with electroporation according to the present invention is able to provide sufficient levels of EPO to result in a maximal hematocrit level.

In this context, there are additional distinctive points by which Fewell et al. differs from claim 1. For example, Fewell et al. used electroporation to transfer the poly-L-glutamic acid formulated plasmid into the cells. Electroporation delivers substances into the cytoplasm, not to the endosome-lysosome compartment which would not allow the composition to accumulate in the lysosomal compartment. Without the accumulation in the lysosomal compartment, the

composition would not be taken up by kidney proximal tubular cells by endocytosis, and therefore would not induce the stimulation or proliferation of fibroblasts resulting in production of erythropoietin. As such, contrary to the Office Action's allegations, Fewell et al. fails to disclose subject matter which naturally includes functions that are newly cited or are identical to the currently claimed composition. Applicants therefore submit that the current rejection fails the tests described in *In re Best* and *In re Fitzgerald* cited in the Office Action.

For all the reasons described above, Applicants submit that Fewell et al. fails to disclose every feature of claim 1. Therefore, Fewell et al. fails to anticipate claim 1. As such, Applicants respectfully request withdrawal of the rejection of claim 1.

Claims 2-5, 19, 21, 23, 24, 26 and 29

Claim 2, from which claims 3-5, 19, 21, 23, 24, 26 and 29depend, recites:

> A composition comprising an erythropoietin production inducing peptide (EPIP), wherein the EPIP comprises poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid, poly-L-aspartic acid, or a mixture of both.

As defined in the instant specification, EPIPs are "peptides that are capable of directly or indirectly stimulating proliferation of fibroblasts, which in turn produce erythropoietin." Thus, an EPIP is a peptide that induce production of erythropoietin.

Fewell et al. describes the ability of poly-L-glutamate to increase the expression of a non-viral erythropoietin gene where a plasmid containing the mEPO coding sequence was formulated in poly-L-glutamate. The results of injecting mice with the poly-L-glutamate formulated plasmid showed that mEPO expression was increased as compared to mice injected with a plasmid containing the mEPO coding sequence was formulated in saline.

The Office Action alleges that the ordinary artisan would reasonably conclude that the

cells comprise poly-L-glutamic acid and the cells are capable of expressing Ep due to the presence of the Ep-encoding vector and therefore Fewell et al. meets the limitations of claim 1. Applicants submit that such a reasoning is flawed.

First, as described above EPIPs are peptides that are capable of directly or indirectly stimulating proliferation of fibroblasts, which in turn produce erythropoietin. Nowhere, in Fewell et al., is there any description or suggestion that fibroblast proliferation was stimulated by the poly-L-glutamate formulated plasmid. The Office Action has completely overlooked this limitation. EPIPs are not simply peptides that produce erythropoietin themselves, like the poly-L-glutamate formulated plasmid of Fewell et al.. EPIPs are peptides that directly or indirectly stimulating proliferation of fibroblasts, which in turn produce erythropoietin. At least for this reason, Fewell et al. fails to anticipate claims 2-5, 19, 21, 23, 24, 26 and 29.

Applicants further submit that Fewell et al. states:

> In one embodiment of the invention, the disease is characterized by insufficient levels of red blood cells resulting in anemia. Delivery of a nucleic acid encoding erythropoietin ("EPO") formulated in poly-L-glutamic acid and delivered in conjunction with electroporation according to the present invention is able to provide sufficient levels of EPO to result in a maximal hematocrit level.

In this context, there are additional distinctive points by which Fewell et al. differs from 2-5, 19, 21, 23, 24, 26 and 29. For example, Fewell et al. used electroporation to transfer the poly-L-glutamic acid formulated plasmid into the cells. Electroporation delivers substances into the cytoplasm, not to the endosome-lysosome compartment which would not allow the composition to accumulate in the lysosomal compartment. Without the accumulation in the lysosomal compartment, the composition would not be taken up by kidney proximal tubular cells by endocytosis, and therefore would not induce the stimulation or proliferation of fibroblasts resulting in production of erythropoietin. As such, contrary to the Office Action's allegations,

Fewell et al. fails to disclose subject matter which naturally includes functions that are newly cited or are identical to the currently claimed composition. At least for this reason, Applicants submit that the current rejection fails the tests described in *In re Best* and *In re Fitzgerald* cited in the Office Action.

Applicants also submit that Fewell et al. discloses a plasmid containing the mEPO coding sequence was formulated in poly-L-glutamate. In other words, the poly-L-glutamate in the Fewell et al. formulated plasmid acts only as a carrier, while the desired effect is brought about by the plasmid containing the mEPO coding sequence conjugated to the carrier. In this respect, it should be noted that polymer compounds such as polyglutamic acid, and other polyamino acids, as well as dextrans have been used to deliver not only nucleic acids, but also anti-cancer drugs (McCormick-Thomson and Duncan, *Journal of Bioactive and Compatible Polymers* 4:252-268, 1989; McCormick-Thomson et al, *Bioactive and Compatible Polymers* 4:242-251, 1998). It is important to note that none of those studies, including the one by Fewell et al. showed that such use of poly-D-glutamic acid as a carrier induced proliferation of peritubular fibroblast-like cells in the kidney that is associated with the production of erythropoietin.

Additionally, Applicants submit that Fewell et al. used electroporation to transfer the poly-L-glutamic acid formulated plasmid into the cells. Electroporation delivers substances into the cytoplasm, not to the endosome-lysosome compartment which would not allow the composition to accumulate in the lysosomal compartment. Without the accumulation in the lysosomal compartment, the composition would not be taken up by kidney proximal tubular cells by endocytosis, and therefore would not induce the stimulation or proliferation of fibroblasts resulting in production of erythropoietin. As such, contrary to the Office Action's allegations, Fewell et al. fails to disclose subject matter which naturally includes functions that are newly

cited or are identical to the currently claimed composition. At least for this additional reason, Applicants therefore submit that the current rejection fails the tests described in *In re Best* and *In re Fitzgerald* cited in the Office Action.

For all the reasons described above, Applicants submit that Fewell et al. fails to disclose every feature of claims 2-5, 19, 21, 23, 24, 26 and 29. Therefore, Fewell et al. fails to anticipate claims 2-5, 19, 21, 23, 24, 26 and 29. As such, Applicants respectfully request withdrawal of the rejection of claims 2-5, 19, 21, 23, 24, 26 and 29.

Rejection Under 35 U.S.C. § 103

1. Claims 1-5, 15, 19, 21, 23, 24, 26, 27, 29, 30, 32-36, 37-39, 103 and 104 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fewell et al. (WO 01/66149) in view of evidence from the 1998 Sigma Catalog. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Claims 30, 32-39 and 103 have been canceled. Applicants submit that the cancelation of claims 37-39 and 103 renders the rejection moot.

Applicants note that the rejection applies Fewell et al. in view of evidence from the 1998 Sigma Catalog in the same way and for the same disclosure for which Fewell et al. in

view of evidence from the 1998 Sigma Catalog was applied in the rejection under 35 U.S.C. § 102 above. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Fewell et al. in view of evidence from the 1998 Sigma Catalog fails to disclose or suggest every limitation of claims 1-5, 15, 19, 21, 23, 24, 26, 27, 29, and 104. Specifically, Fewell et al. alone or in combination with the 1998 Sigma Catalog fails to disclose or suggest a composition comprising erythropoietin and an erythropoietin production inducing peptide (EPIP). In addition, Fewell et al. alone or in combination with the 1998 Sigma Catalog fails to disclose or suggest a composition comprising an erythropoietin production inducing peptide (EPIP), wherein the EPIP comprises poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid, poly-L-aspartic acid, or a mixture of both.

The common knowledge of one of skill in the art does not make up for the deficiencies found in Fewell et al. in view of the 1998 Sigma Catalog. Applicants further note that claims 3-5, 15, 19, 21, 23, 24, 26, 27, 29, and 104 depend from claim 2, and therefore contains all the limitations of claim 2. Thus, Fewell et al. and the 1998 Sigma Catalog, either alone or in combination, fail to disclose or suggest each and every element of claims 1, 2, 3-5, 15, 19, 21, 23, 24, 26, 27, 29, and 104. Applicants respectfully request withdrawal of the rejection.

2. Claims 1-5, 19, 21, 23, 24, 26, 28, 29, 30, 33-35, 37-39, 103 and 104 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fewell et al. (WO 01/66149) in view of evidence from the 1998 Sigma Catalog in view of Maskiewicz et al. (US 2001/0038859). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in

the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Claims 30, 33-35, 37-39 and 103 have been canceled. Applicants submit that the cancelation of claims 30, 33-35, 37-39 and 103 renders the rejection moot.

Maskiewicz et al. discloses stable protein or nucleic acid formulations wherein the compound remains in stable, dry powder form, yet the formulation is flowable and, therefore amenable to delivery to an animal via injection, transdermal administration, oral delivery or using an implantable device for sustained delivery.

Applicants note that the rejection applies Fewell et al. in view of evidence from the 1998 Sigma Catalog in the same way and for the same disclosure for which Fewell et al. in view of evidence from the 1998 Sigma Catalog was applied in the rejection under 35 U.S.C. § 102 above. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Fewell et al. in view of evidence from the 1998 Sigma Catalog fails to disclose or suggest every limitation of claims 1-5, 15, 19, 21, 23, 24, 26, 27, 29, and 104.

Specifically, Fewell et al. alone or in combination with the 1998 Sigma Catalog fails to disclose or suggest a composition comprising erythropoietin and an erythropoietin production inducing peptide (EPIP). In addition, Fewell et al. alone or in combination with the 1998 Sigma Catalog fails to disclose or suggest a composition comprising an erythropoietin production inducing peptide (EPIP), wherein the EPIP comprises poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid, poly-L-aspartic acid, or a mixture of both.

Maskiewicz et al., which was cited for disclosing formulations for pharmaceutical

compositions comprising protein or DNA wherein the compositions remain in a dry stable powder form until used for administration, does not make up for the deficiencies found in Fewell et al. in view of the 1998 Sigma Catalog.

Applicants note that claims 3-5, 15, 19, 21, 23, 24, 26, 28, 29 and 104 depend from claim 2, and therefore contains all the limitations of claim 2. Thus, Fewell et al. in view of the 1998 Sigma Catalog and Maskiewicz et al., either alone or in combination, fail to disclose or suggest each and every element of claims 1, 2, 3-5, 15, 19, 21, 23, 24, 26, 28, 29 and 104. Applicants respectfully request withdrawal of the rejection.

3. Claims 1-5, 19, 21-26, 29, 30, 33-35, 37-39, 103 and 104 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fewell et al. (WO 01/66149) in view of evidence from the 1998 Sigma Catalog in view of Sims et al. (US 6,080,557). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Claims 30, 33-35, 37-39 and 103 have been canceled. Applicants submit that the cancelation of claims 30, 33-35, 37-39 and 103 renders the rejection moot.

Sims et al. discloses purified and isolated IL-1/TNF-.alpha.-activated kinase (ITAK), nucleic acids encoding ITAK, processes for production of recombinant forms of ITAK, pharmaceutical compositions containing ITAK, and use of ITAK in therapies and in various

assays, including assays to detect antagonists and agonists of ITAK.

Applicants note that the rejection applies Fewell et al. in view of evidence from the 1998 Sigma Catalog in the same way and for the same disclosure for which Fewell et al. in view of evidence from the 1998 Sigma Catalog was applied in the rejection under 35 U.S.C. § 102 above. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Fewell et al. in view of evidence from the 1998 Sigma Catalog fails to disclose or suggest every limitation of claims 1-5, 19, 21-26, 29 and 104.

Specifically, Fewell et al. alone or in combination with the 1998 Sigma Catalog fails to disclose or suggest a composition comprising erythropoietin and an erythropoietin production inducing peptide (EPIP). In addition, Fewell et al. alone or in combination with the 1998 Sigma Catalog fails to disclose or suggest a composition comprising an erythropoietin production inducing peptide (EPIP), wherein the EPIP comprises poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid, poly-L-aspartic acid, or a mixture of both.

Sims et al., which was cited for teaching representative carriers for injectable solutions of composition for gene therapy, does not make up for the deficiencies found in Fewell et al. in view of the 1998 Sigma Catalog.

Applicants note that claims 3-5, 19, 21-26, 29 and 104 depend from claim 2, and therefore contains all the limitations of claim 2. Thus, Fewell et al. in view of the 1998 Sigma Catalog and Sims et al., either alone or in combination, fail to disclose or suggest each and every element of claims 1, 2, 3-5, 19, 21-26, 29 and 104. Applicants respectfully request withdrawal of the rejection.

4. Claims 1-5, 19-21, 23, 24, 26, 29, 30, 33-35, 37-39, 103 and 104 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fewell et al. (WO 01/66149) in view of evidence

from the 1998 Sigma Catalog in view of Ding et al. (US 2003/0219407). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Claims 30, 33-35, 37-39, and 103 have been canceled. Applicants submit that the cancelation of claims 30, 33-35, 37-39 and 103 renders the rejection moot.

Ding et al. discloses recombinant DNA constructs for inactivation of viral or endogenous genes in a cell, wherein the construct comprises viral sequence sufficient to activate RNA silencing.

Applicants note that the rejection applies Fewell et al. in view of evidence from the 1998 Sigma Catalog in the same way and for the same disclosure for which Fewell et al. in view of evidence from the 1998 Sigma Catalog was applied in the rejection under 35 U.S.C. § 102 above. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Fewell et al. in view of evidence from the 1998 Sigma Catalog fails to disclose or suggest every limitation of claims 1-5, 19, 21-26, 29 and 104.

Specifically, Fewell et al. alone or in combination with the 1998 Sigma Catalog fails to disclose or suggest a composition comprising erythropoietin and an erythropoietin production inducing peptide (EPIP). In addition, Fewell et al. alone or in combination with the 1998 Sigma Catalog fails to disclose or suggest a composition comprising an erythropoietin production

inducing peptide (EPIP), wherein the EPIP comprises poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid, poly-L-aspartic acid, or a mixture of both.

Ding et al., which was cited for disclosing that it is desirable to formulate compositions for gene therapy with a preservative such as phenol, does not make up for the deficiencies found in Fewell et al. in view of the 1998 Sigma Catalog.

Applicants note that claims 3-5, 19, 21, 23, 24, 26, 29 and 104 depend from claim 2, and therefore contains all the limitations of claim 2. Thus, Fewell et al. in view of the 1998 Sigma Catalog and Ding et al., either alone or in combination, fail to disclose or suggest each and every element of claims 1, 2, 3-5, 19, 21, 23, 24, 26, 29 and 104. Applicants respectfully request withdrawal of the rejection.

Favorable consideration of claims 1-5, 15, 19-29 and 104 is earnestly solicited.

A Credit Card Payment Via EFS-Web authorizing payment in the amount of $65, which represents the small entity fee pursuant to 37 C.F.R. § 1.17(a)(1) for a one-month extension of time along with a Request for One Month Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

BALLARD SPAHR LLP

/Scott D. Marty, Reg. No. 53,277/
Scott D. Marty
Registration No. 53,277

BALLARD SPAHR LLP
Customer Number 23859
(678) 420-9300
(678) 420-9301 (fax)

CERTIFICATE OF ELECTRONIC TRANSMISSION UNDER 37 C.F.R. § 1.8			
I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted via electronic transmission via EFS-Web on the date indicated below.			
Name of Person Mailing (Print/Type)	Scott D. Marty, Ph.D.		
Signature	/Scott D. Marty, Reg. No. 53,277/	Date	May 17, 2011